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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,740	04/15/2004	Willa Fabian	P-9621.05	7058

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MEDTRONIC, INC.
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EXAMINER	
LAYNO, CARL HERNANDZ	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,740	FABIAN ET AL.	
	Examiner	Art Unit	
	Carl H. Layno 12/27/05	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8 and 11* is/are rejected.

7)☒ Claim(s) *4,6,7,9 and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority as a Continuation of US Patent No. 6,735,749, filed August 31, 2001, which claims priority filing based upon U.S Patent Application Publication 2002/0049482 A1, filed on April 25, 2002, and upon U.S Provisional Application No. 60/211,410, filed on June 14, 2000.

2. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/944,720, filed August 31, 2001. **A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c).** See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the

date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. **Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by**

filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

3. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on March 14, 2005.

Drawings

4. Applicant's formal drawings were received by the Office on April 15, 2004 and have been approved by the Examiner.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, line 2 of claim 11 refers to the acronym "ILR" without first defining what this means. To overcome this rejection, the Examiner recommends replacing "ILR" with the words "insertable loop recorder (ILR)".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1, 3, 5, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Chistopherson et al (US 6,805,667).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In regard to claims 1 and 3, the Christopherson et al (US 6,805,667) patent describes a system for monitoring patient medical data remotely (Fig.1) including at least three medical

device (IMD) **10, 10', 10"** implanted in a patient **12**, an information remote monitor (IRM) **20**, which performs the function of applicant's "home monitoring system" (col.7, lines 66-67) by wirelessly communicating with the implantable device **18'** (col.8, lines 24-38), and a remote PC/"expert station" **27** thru a bi-directional serial line **22** (Figs. 1 and 2). The IRM **20** includes a visual LCD display screen and front panel LEDs, as well as a speaker/beeper for audible indications (see block **90** of Fig.7). Alternatively, the IRM may also communicate via telephone lines through ports **66** (Fig.4B) to a remotely located clinical center for follow-up monitoring and evaluation (Abstract, lines 5-7).

In regard to claim 5, the IRM **20** is equipped with an external pressure reference (EPR) **24** (Fig.2) for sensing barometric pressure (col.8, lines 6-10).

In regard to claim 11, Christopherson et al defines the implantable medical devices **10**, **10'**, and **10"** as being a cardiac device, a drug delivery device, and a neurological drug device (col.7, lines 6-9) among other possible devices.

Claim Rejections - 35 USC § 103

9. Claim 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable Webb et al (US 6,599,250) or Scarantino et al (US 6,402,689) in view of Greeninger et al (US H1347) (all references were cited as prior art by the Applicant).

The Webb et al (US 6,599,250) patent, cited by the applicant as prior art, describes a system (Fig.1B) for monitoring a patient's heart condition including an implantable medical device **20** (IMD), a home monitoring instrument **24**, and a remote clinician's station **28**. Through instrument **24**, the patient can obtain visual feedback by accessing an internet web

portal **52** (Fig.3), which enables browsing of pertinent medical information in the Medtronic database. See Figs.4A and 4B in addition to paragraphs [0039] and [0040].

The Scarantino et al (US 6,402,689) patent, also cited by the applicant as prior art, describes a system for monitoring patient data including applicant's claimed features of an implantable medical device **50** (Fig.1A,1B) by using a bedside/home monitoring system **75,75'**, and a remote expert station **80**. The unit **75'** can be programmed to produce verbal feedback to the patient (col.12, lines 40-42).

The Greeninger et al H1347 Statutory Invention Registration, cited by the applicant as prior art, describes a system (Fig.1) includes an external programmer **10** for monitoring an implantable medical device **16**. the external programmer **10** is equipped with a display **102** and speaker **110** (Fig.2) for providing both diagnostic data and verbal feedback in any number of different languages (col.4, lines 22-24).

To have modified both the Webb et al and the Scarantino et al home monitoring systems with a combination of visual and verbal feedback would have been an obvious modification to one of ordinary skill in the art in view of the teachings of Greeninger et al which shows that this combination of features is well known in the art of external programmer/monitors which communicate with implantable medical devices (IMDs).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application

claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1, 2, and 11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, and 7, respectively, of U.S. Patent No. 6,735,479. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite the same hardware of: 1) at least one implantable device, 2) a home monitoring system, 3) a "means for providing visual and verbal feedback", 4) a "remote expert station" in bi-directional communication with the "implanted device" and "home monitoring system". In addition, depending claims 2 and 11 recite the same limitations of "continuously" providing patient data to the home monitoring system (claim 2) and specifying that the implanted device include either a pacemaker, ILR, defibrillator, drug pump, neruostimulator, or hemodynamic monitor (claim 11), as found in claims 8 and 7, respectively, of U.S Patent 6,735,479.

Allowable Subject Matter

12. Claims 4, 6, 7, 9, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Linberg US 6,442,433 and Nelson et al US 6,480,745 patents are cited for their pertinent description of patient monitoring systems which communicate implantable medical device data through home monitoring devices to remote users. It is not clear from these patents whether or not "means for providing visual and verbal feedback" are integrated with their home monitoring systems.

The Sweeney et al US 6,285,909 patent is cited for its teaching of storing a patient's long term cardiac trends (col.4, lines 25-30) in order to help a physician diagnose and treat pathophysiologic conditions. Unlike applicant's system, the device of Sweeney et al is not in communication with a "remote expert station".

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carl H. Layno

CARL LAYNO
PRIMARY EXAMINER

CHL
12/27/2005